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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,795	09/05/2001	Gunther Berndl	49727	4232

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 11/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,795	BERNDL ET AL.	
	Examin r	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Request for Continued Examination received on October 9, 2002 is acknowledged. Claims 1-6 are included in the prosecution of this application.

Response to Arguments

Applicant's arguments with have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites at least 10% of the active is complexed to the cyclodextrin. Claim 6 depends from claim 1 which recites the limitation the active is uncomplexed by cyclodextrin. Further, claims have been specifically amended to recite the uncomplexed limitation in independent claim 1; therefore clarification is requested to the apparent disparity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 5-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Stella et al (6,046,177).

Stella et al disclose a sulfoalkyl ether cyclodextrin (SAE-CD) based controlled release pharmaceutical formulation. The formulation contains 2.5% of an active, 67.5% of SAE-CD, 10.5% PEG 6000, and excipients. The material is mixed without a solvent, passed thorough an extruder, and shaped into a tablet. (Note example 10). Stella et al disclose that major portion (lower limit 50% and preferably greater than 95%) of the SAE-CD is not complexed to the active agent (col. 12, lines 9-22).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stella et al (6,046,177) in view Klimesh et al (4880585).

As set forth above, Stella et al disclose a sulfoalkyl ether cyclodextrin (SAE-CD) based controlled release pharmaceutical formulation. The formulation contains 2.5% of an active, 67.5% of SAE-CD, 10.5% PEG 6000, and excipients. Plasticizers are added to lower the temperature to 150 degrees Celsius (col. 27, lines 31-40). The material is mixed without a solvent, passed thorough an extruder, and shaped into a tablet. (Note

example 10). Stella et al disclose that major portion (lower limit 50% and preferably greater than 95%) of the SAE-CD is not complexed to the active agent (col. 12, lines 9-22).

Stella et al do not specify the type of extruder used to shape the solid dosage form.

Klimesh et al teaches a method of continuous tableting using a molding calendar with opposite rollers (col. 1, lines 16-27). The reference teaches the use of pharmaceutical mixtures containing instant polymeric binders and instant temperature to facilitate the process (col. 2, lines 40-68). The advantage of the process is that it eliminates premixing (col. 1, lines 28-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Stella et al and Klimesh et al. One would be motivated to do so since Klimesh et al teaches the advantages using mold calendaring to make tablets via a simple process. Further, one would be motivated to do so with similar results since Stella teaches the same binders and temperature when extruding the SAE-CD formulation and Klimesh teaches acceptable polymers for use in the molding calendars.

Claims 1, 2, and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stella et al (5,874,418) in view of Stella et al (6,046,177).

Stella '418 teaches a SAE-CD and active formulation wherein a major portion of the SAE-CD is not complexed to the cyclodextrin. The lower limit of uncomplexed portion is greater than 50% and the preferable amount is greater than 95% (column 7,

lines 40-60). The ratio of the SAE-CD to active is taught on column 7, lines 40-46. The therapeutic compound is in the amount of 0.1-50% (col. 13, line 45). Instant amounts of active, cyclodextrin, and excipients are taught (examples). PVP is taught as a binder on column 17, line 19. Plasticizers are added to lower the temperature to 150 degrees Celsius (col. 17, lines 41-50). The solid dosage form is made without the use of solvents (examples).

The instant amount of polymeric binder is not taught.

Stella '177 discloses SAE-CD based controlled release pharmaceutical formulation. The formulation contains 2.5% of an active, 67.5% of SAE-CD, 10.5% PEG 6000, and excipients. Stella teaches the binder is used as a release rate modifier to provide the desired release profile (col. 27, lines 40-50). Plasticizers are added to lower the temperature to 150 degrees Celsius (col. 27, lines 31-40). The material is mixed without a solvent, passed thorough an extruder, and shaped into a tablet. (Note example 10). Stella et al disclose that major portion (lower limit 50% and preferably greater than 95%) of the SAE-CD is not complexed to the active agent (col. 12, lines 9-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to increase the amount of polymeric binder since Stella '177 teaches the use of binders as release rate modifiers. One would be motivated to do so to yield the desired release profile. Further, one would be motivated to do so with the expectation of similar results is high since both formulation are similar.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stella et al (5,874,418) in view of Stella et al (6,046,177) in further view of Klimesh et al (4880585).

As set forth above, the Stella reference teach cyclodextrin formulations.

The references do not specify the type of extruder used to shape the solid dosage form.

Klimesh et al teaches a method of continuous tableting using a molding calendar with opposite rollers (col. 1, lines 16-27). The reference teaches the use of pharmaceutical mixtures containing instant polymeric binders and instant temperature to facilitate the process (col. 2, lines 40-68). The advantage of the process is that it eliminates premixing (col. 1, lines 28-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Stella et al and Klimesh et al. One would be motivated to do so since Klimesh et al teaches the advantages using mold calendaring to make tablets via a simple process. Further, one would be motivated to do so with similar results since Stella teaches the same binders and temperature when extruding the SAE-CD formulation and Klimesh teaches acceptable polymers for use in the molding calendars.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG

November 20, 2002

MICHAEL G. HARTLEY
PRIMARY EXAMINER